

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:) Group Art Unit: 1614
José Zayas-Rivera, et al.)
Application No.: 10/016,726) Examiner: Kevin E. Weddington
Filed: October 30, 2001)
For: MEDICAL APPLICATION OF) **DECLARATION OF JOSÉ ZAYAS-**
OXIDIZED MONOTERPENES) **RIVERA, PH.D.**
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I, José Zayas-Rivera, Ph.D., do hereby declare as follows:

1. I one of the inventors in U.S. Patent Application No. 10/016,726, titled "Medical Application of Oxidized Monoterpenes," filed October 30, 2001 (the '726 application).

2. I hold a Ph.D. from The Ohio State University in Organic Chemistry and a Post-Doctoral Degree from Princeton University in Organic Chemistry. I have worked as a consultant in the pharmaceutical field for 19 years. I am skilled in the art of the above-identified application.

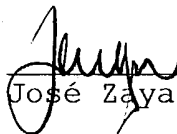
3. The terms "inactive ingredient" are used in the '726 application. These terms are commonly used and well

understood by those skilled in this art. Indeed, these terms are defined by regulation at 21 C.F.R. §210.3(b)(8) as "any component of a drug product other than the active ingredient."

4. As those skilled in the art are well aware, the Food and Drug Administration (FDA) maintains a listing of inactive ingredients. This listing is available through the FDA's Internet web site at: <http://www.fda.gov/cder/iig/iigfaqWEB.htm>. At the time this declaration is being filed, there are over seven hundred (700) inactive ingredients identified by the FDA.

4. I declare under penalty of perjury under the laws of the United States of America that the forgoing is true and correct.

April 7, 2004
Date



José Zayas-Rivera